

Appl. No. 10/539,797
Amendment dated: April 28, 2009
Reply to OA of: October 29, 2008

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1-13 (Cancelled)

14 (Currently Amended). An assay method for the determination of calprotectin in a calprotectin-containing body fluid, said method comprising the steps of:

(a) obtaining a calprotectin-containing liquid sample of, or derived from, said fluid;
(b) contacting said sample of said body fluid with ~~a nanoparticle-bound anti-calprotectin antibody~~ antibodies or antibody fragment, fragments to bind said calprotectin, wherein said anti-calprotectin antibodies or antibody fragments are immobilised by binding or coupling, either directly or indirectly, to nanoparticles to form antibody or antibody fragment coated nanoparticles; and

(c) assessing the calprotectin content by turbidimetry,
wherein the diameter of the antibody or antibody fragment coated nanoparticles is in the range 65-140 nm.

15 (Currently Amended). A The method ~~as claimed in~~ of claim 14 wherein the diameter of the antibody or antibody fragment coated nanoparticles is in the range 75-120 nm.

16 (Currently Amended). A The method ~~as claimed in~~ of claim 14 wherein said nanoparticles are substantially all of the same size. ~~(e.g. monodisperse).~~

17 (Currently Amended). A The method ~~as claimed in~~ of claim 14 wherein an opacity enhancer is added in between steps (b) and (c)

18 (Currently Amended). A The method ~~as claimed in~~ of claim 14 wherein said body fluid is selected from blood, serum, plasma, urine, cerebrospinal fluid, oral fluid, synovial fluid or empyema fluid.

19 (Currently Amended). A The method ~~as claimed in~~ of claim 14 performed as an automated assay.

20 (Currently Amended). A kit for use in a diagnostic assay method according to claim 14 comprising:
one or more anti-calprotectin antibody- or antibody fragment-coated nanoparticles having a diameter in the range 65-140 nm,

wherein said assay method comprises;

- (a) obtaining a calprotectin-containing liquid sample of, or derived from, said fluid;
- (b) contacting said sample of said body fluid with said nanoparticle-bound anti-calprotectin antibody or antibody fragment, to bind said calprotectin; and
- (c) assessing the calprotectin content by turbidimetry.

21 (Currently Amended). A The kit ~~as claimed in~~ of claim 20 further comprising a calprotectin solution of known concentration or a set of such solutions having a range of calprotectin concentrations.

22 (Currently Amended). A The kit ~~as claimed in~~ of claim 20 further comprising a light transmitting vessel.

23 (Currently Amended). A The kit ~~as claimed in~~ of claim 20 further comprising an opacification enhancer.

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24 (Currently Amended). A The kit as ~~claimed in~~ of claim 20 further comprising a detector.

25 (Cancelled).

26 (Currently Amended). A method for assessing the potential for or propensity to cardiovascular disease ~~of diagnosis of a disease~~ comprising the method as claimed in claim 14 followed by comparison of said calprotectin content with a predetermined threshold value and correlating a calprotectin concentration above said threshold value with an indication of potential for or propensity to cardiovascular disease. ~~wherein said disease is selected from rheumatic diseases, Sjögrens syndrome, intraocular inflammatory conditions, cystic fibrosis, acute and chronic lung disease, lung carcinoma, pulmonary cancers, colorectal cancer, inflammatory bowel disease, gastric cancer, colorectal adenoma or cancer, Chrohn's disease, ulcerative colitis, gastrointestinal mucosal inflammation, urinary stones, alcoholic liver disease, oral inflammatory mucosal disease, CNS inflammatory disease, HIV infection, secondary CNS infections in HIV infected patients, urinary tract infections, cystitis, pyelonephritis, endogenous posterior uveitis, haematological conditions, febrile conditions (infectious and non-infectious), CVD, acute myocardial infarction and apheresis.~~

27 (Cancelled). A method of diagnosis as claimed in claim 26 wherein said disease is CVD.

28 (New). The method of claim 14 wherein said nanoparticles are monodisperse.